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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/053,291	01/17/2002	Heidi Stuhlmann	A31200-A - 070165.0467	7117

7590 05/26/2004

BAKER BOTTS L.L.P.
44TH FLOOR
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NEW YORK, NY 10112-0228

EXAMINER	
WILSON, MICHAEL C	
ART UNIT	**PAPER NUMBER**
1632	

DATE MAILED: 05/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/053,291	STUHLMANN ET AL.	
	Examiner	Art Unit	
	Michael C. Wilson	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 March 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's arguments filed 3-15-04 have been fully considered but they are not persuasive.

Claims 1-6 remain pending and under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Priority

The amendment filed 1-17-02 inserted a paragraph to the first line of the specification claiming priority to 09/083290, filed May 22, 1998, and mistakenly stated the instant application was filed July 5, 2001.

The amendment filed 3-15-04 corrects the mistake made in the first line of the specification by deleting reference to the filing date of the instant application.

Oath/Declaration

A copy of the original oath/declaration filed in parent application 09/083290 was filed with the instant application.

Specification

The correction to the first line has been entered.

Applicants are required to fill in the blanks in the specification indicating the ATCC Accession Nos. on page 15. In order to make such an amendment, there must be support in the specification for the ATCC Nos. If such support is not present in the specification, applicants are required to submit a declaration stating that they have maintained control and possession of the vector of the ATCC Accession Nos. since the filing date. Otherwise any request to so amend the specification will constitute new matter. Applicants argue the specification was amended in July 31, 2000. Applicants' argument is not persuasive. The instant application was not filed until 1-17-02.

Claim Rejections - 35 USC § 101

Claims 1-6 remain rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility. The specification states the DB1 gene is expressed in human blood cells and adult organs, but the function of the DB1 protein is unknown (pg 6, ¶ 3, of the present specification). The specification states the Vezf1 gene is 98% homologous with the DB1 gene and is expressed during vasculogenesis and angiogenesis (pg 41 and 42). The specification does not provide a function for the Vezf1 or DB1 proteins. It is not clear that the homology between Vezf1 and DB1 is sufficient to give the protein products the same activity. The specification does not compare the homologies of Vezf1 or DB1 proteins with any protein with a known function such that the function of Vezf1 or DB1 could be determined with any certainty. While the DNA claimed in the instant invention may be used to make protein or to test for gene expression, such a use is not of value if the function of the protein is unknown.

Without a readily apparent utility for the protein, it is unclear that the purified and isolated Vezf1 gene (claim 1), the purified and isolated nucleic acid encoding the Vezf1 protein (claim 3) or the expression vector containing the DB1 gene (claim 6) have any utility. The Vezf1 gene and the DB1 gene do not have a known function in the instant invention and consequently do not have a readily apparent utility.

Applicants argue the lack of function attributed to DB1 gene products as a basis for the lack of utility of Vezf1 genes and proteins. Applicants argue the function of Vezf1 is the focus of the present invention (¶ bridging pg 6-7 of response). Applicants' arguments are not persuasive. As an initial matter, the examiner's rejection pointed out the function of DB1 was unknown (see the 3rd line of the basis of the rejection; see pg 6, ¶ 3, of the present specification) and that DB1 shared homology with Vezf1. The basis of the rejection was that the specification and art at the time of filing did not teach the function of the Vezf1 gene.

Applicants argue Vezf1 should not be compared to a protein having a known function in order to determine the functionality of Vezf1 (pg 7, 1st ¶, of response). applicants' argument is flawed because the function of DB1 was not known (pg 6, ¶ 3, of specification). In addition, applicants' argument is not persuasive because the function of Vezf1 is not adequately described in the specification for reasons set forth in the rejection.

Applicants argue the specification describes the function of Vezf1 (pg 7, 2nd ¶, of response). Applicants argue Vezf1 can be used as an endothelial cell marker (pg 7, line

11-13), a diagnostic tool for vascular disorders (pg 7, lines 14-21), to treat vascular disorders (pg 8, lines 7-11). Applicants' arguments are not persuasive.

Pg 7, 3rd full paragraph, states the invention provides for a method of identifying an endothelial cell by identifying expression of Vezf1 RNA or protein in the cell. However, applicants do not provide a reasonable correlation between Vezf1 expression and endothelial cells. The specification and the art at the time of filing do not teach that Vezf1 expression occurs only in endothelial cells; therefore, the asserted utility is not substantial. Pg 41, 1st full ¶, last sentence, states Vezf1 expression correlates to the beginning of blood island formation; it does not state Vezf1 expression in blood islands was limited to endothelial cells. Endocardial cells, which inherently comprise endothelial cells, did not express Vezf1 (¶ bridging pg 41-42, 2nd sentence; AP staining indicates Vezf1 expression as described in the preceding ¶). Strong expression was found in the allantois (pg 42, lines 5-6); however, the specification does not teach expression in the allantois was limited to endothelial cells. The specification concludes that "Vezf1 expression is mainly confined to vascular endothelial cells and their precursors." The term "mainly" in the statement implies more than just endothelial cells express Vezf1 or that non-endothelial cells expressed Vezf1; therefore the asserted utility is not specific. The conclusion that vascular endothelial cells and their precursors express Vezf1 implies that the asserted utility would be generic to vascular endothelial cells and their precursors. Such a utility is not specific to one type of cell because endothelial cells and endothelial cell precursors have different structures and functions. Applicants have merely begun to establish an expression pattern for Vezf1, which in

and of itself is insufficient to establish a specific utility for using the Vezf1 gene as a marker for endothelial cells because Vezf1 gene expression is generic to vascular endothelial cells, their precursors and possibly other types of cells that have not been tested, and because Vezf1 expression did not occur in endothelial cells of the endocardium (¶ bridging pg 41-42).

Pg 7, 4th full paragraph, discusses using the Vezf1 gene to diagnose vascular disease. However, the specification and the art at the time of filing do not correlate Vezf1 expression with any vascular disease; therefore, the asserted utility is not specific to any vascular disease. In addition, the specification does not teach whether vascular disease correlates with overexpression or lack of expression of Vezf1; therefore, the asserted utility is not substantial. Finally, the specification does not describe any vascular diseases linked to overexpression of Vezf1 or a disruption in Vezf1; therefore, the asserted utility is not substantial.

Pg 7, 4th full paragraph, discusses using Vezf1 to treat vascular disease. However, the specification and the art at the time of filing do not correlate Vezf1 with any vascular disease; therefore, the asserted utility is not specific to any vascular disease. In addition, the specification does not teach whether vascular disease correlates with an excess or an absence of Vezf1; therefore, the asserted utility is not substantial. Finally, the specification does not describe any vascular diseases linked to an excess or an absence of Vezf1; therefore, the asserted utility is not substantial.

Applicants' arguments regarding the Declaration by Dr. Stuhlmann are not persuasive. First, the declaration cannot be found. Furthermore, applicants' arguments

imply that endothelial cells only express Vezf1 when proliferation is required which is not described in the specification. The specification concludes that "Vezf1 expression is mainly confined to vascular endothelial cells and their precursors;" the specification does not conclude that Vezf1 expression is limited to proliferating vascular endothelial cells.

Applicants argue the structure of Vezf1 implies it regulates vascular endothelial cells throughout development (1st ¶ on pg 8 of response). Therefore, applicants conclude Vezf1 has a use as a regulator of vascular endothelial cells during development. Applicants' argument is not persuasive. The specification does not teach how to use Vezf1 to regulate vascular endothelial cells throughout development. In addition, Vezf1 is not limited to developing vascular endothelial cells (see adult tissues in ¶ bridging pg 43-44 and in Fig. 13).

Applicants' arguments regarding recent data obtained from Vezf1 knockout mice (pg 8, 2nd full ¶) is moot because the recent data was not available at the time of filing. Finding a utility for Vezf1 after filing the application is not sufficient. In addition, the findings obtained from Vezf1 knockout mice are not specific to any vascular endothelial disease.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

No claim is allowed.

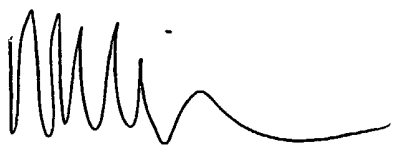
Inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Wilson who can normally be reached on Monday through Friday from 9:00 am to 5:30 pm at 571-272-0738.

Questions of a general nature relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.

If attempts to reach the examiner, patent analyst or Group receptionist are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached on 571-272-0804.

The official fax number for this Group is (703) 872-9306.

Michael C. Wilson



MICHAEL WILSON
PRIMARY EXAMINER